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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/241,595	02/02/1999	JORG REIMANN	9325-0008.30	8928
1444	7590	07/13/2005	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			WEHBE, ANNE MARIE SABRINA	
		ART UNIT		PAPER NUMBER
				1633

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/241,595	REIMANN ET AL.
	Examiner	Art Unit
	Anne Marie S. Wehbe	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 18 April 2005.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,4-10,17-19,22-27,29-33 and 35 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 1,4-10,27,29,30,32 and 33 is/are allowed.

6) Claim(s) 17-19, 25-26, 31, and 35 is/are rejected.

7) Claim(s) 22-24 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

**DETAILED ACTION**

Applicant's amendment and response received on 4/18/05 has been entered. Claims 2-3, 11-16, 20-21, 28 and 34 are canceled. Claims 1, 4-10, 17-19, 22-27, 29-33, and 35 are currently pending in the instant application. An action on the merits follows.

Those sections of Title 35, US code not included in this action can be found in the previous office action.

***Claim Rejections - 35 USC § 112***

The rejection of claims 27, and 29-30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of applicant's amendments to the claims.

***Claim Rejections - 35 USC § 102***

The rejection of claims 1, 4-11, 14-19, 22-26, and 31-35 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,039,522 (8/13/91), hereafter referred to as Neurath et al., as evidenced by Schirmbeck et al. (1996) Intervirology, Vol. 39 (1), 111-119, is withdrawn over claims 1, 4-11, 14-16, 22-24, and 32-33 in view of applicant's cancellation of the claims, arguments, or amendment of the claims to recite that the HBsAg particles are incubated at

about 35°C and about 60 °C, and **maintained** over claims 17-19, 25-26, 31, and 35.

Applicant's amendments and arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection over claims 17-19, 25-26, 31, and 35 for reasons discussed in detail below.

The applicant argues that claims 17-19, 22-26, and 35 are composition claims that positively recite for the presence of three materials, the HBsAg particle, the biologically active material and the immunostimulatory molecule, and that Neurath does not teach entrapping two materials in HBsAg particles. In response, it is noted that claims 22-24, which recite that the immunostimulatory molecule is a cytokine, oligonucleotide, or toxin, have been withdrawn from this rejection. In regards to the remaining composition claims, claim 17, upon which claims 18-19, 25-26, and 35 depend, recites a composition comprising an HBsAg particle in which a biologically active molecule and an immunostimulatory molecule are either entrapped within the interior of the HBsAg particle or exposed or present at the surface of the HBsAg particle. The claims as written, unlike claim 8 which has been amended to clearly indicate that the biologically active molecule and the immunostimulatory molecule are not the same molecule, reads on an HBsAg particle in which the biologically active molecule and the immunostimulatory molecule are the same, as long as more than one of the molecules is present. As such, Neurath anticipates the claimed compositions by teaching immunogenic compositions comprising myristilated viral antigens absorbed into HBsAg particles such that antigen is present the surface of the HBsAg particle. As noted in the previous office action, viral antigens are inherently considered immunostimulatory molecules as their expression results in the generation of immune responses.

It is further noted that the rejection of claim 31 has not been addressed by the applicant.

Claim 31 has not been amended to recite the limitation that the HBsAg particle and the biologically active molecule are incubated at about 35°C and about 60 °C. Thus, the rejection of record stands over claim 31.

***Allowable Subject Matter***

Claims 1, 4-10, 27, 29-30, and 32-33 are considered free of the prior art of record and allowable at this time. In particular, claims 1, 4-10, 27, 29-30, and 32-33 are free of the prior art of record because the closest prior art, Neurath et al., fails to teach or suggest incorporating/encapsulating a biologically active molecule into HBsAg particles by incubating HBsAg particles with the biologically active molecule at about 35°C and about 60 °C.

Claims 22-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In regards to claims 22-24, the prior art, while teaching the noncovalent incorporation of antigens into HBsAg particles (Neurath) and the use of cytokines, immunostimulatory oligonucleotides, or cholera toxin as adjuvants to enhance immune responses to antigens, does not teach or reasonably suggest specifically incorporating or encapsulating these adjuvants in HBsAg particles noncovalently in combination with antigens. Note as well

that Neurath only teaches the incorporation of myristolated antigen into the HBsAg particles. Thus, the subject matter of claims 22-24 is considered free of the prior art of record.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300.** Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

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Dr. A.M.S. Wehbé

ANNE M. WEHBE, PH.D  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Anne M. Wehbé". A thin line extends from the end of the signature towards the right side of the page.